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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,055	02/18/2004	Stephen Johnston	UTSD:788US	9475

32425 7590 04/14/2006

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EXAMINER	
MCGILLEM, LAURA L	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/781,055	JOHNSTON ET AL.	
	Examiner	Art Unit	
	Laura McGillem	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *22-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/19/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to comply*.

DETAILED ACTION

It is noted that the raw sequence listing, filed 3/7/2006, was found to be in error because the length of SEQ ID NO:38 was listed as 11 nucleotides in length when SEQ ID NO:38 is actually 21 nucleotides in length. For purposes of sequence searching by STIC and subsequent examination, the length of SEQ ID NO:38 was confirmed and edited to 21 nucleotides by the Examiner.

Priority

It is noted that this Application receives priority to Provisional Application No. 60/448/166, filed 02/18/2003.

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-21) in the reply filed on 3/3/2006 is acknowledged.

Claims 22-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/3/2006.

Applicant's election without traverse of the specific binding element having the promoter sequence of SP72 (SEQ ID NO:35) and the genetic immunization vector in the reply filed on 3/3/2006 is acknowledged.

The species election requirement is hereby withdrawn.

Claims 1-21 are under examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 21 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 21 does not sufficiently distinguish over nucleic acid segments that exist naturally because the claim does not particularly point out any non-naturally occurring differences between the claimed product and the naturally occurring products. The nucleic acid segments can be in a human and claims reading on *in vivo* human tissue are non-statutory because the claims read on part of a living human being *in situ*. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "isolated " or "purified". See MPEP 2105.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 -5, 7-14 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-5 are vague and indefinite because they recite the phrase "downstream promoter element" and "upstream binding element" and as the claim is written, it does not recite a gene operably linked to the claimed elements, therefore it is not clear what is meant by "downstream" or "upstream".

Claims 2-5 are vague and indefinite because they recite the phrase "upstream binding element" and it is not clear to what the binding element binds. As the claim is written, an "upstream binding element" is a binding element to which "upstream" binds.

Claims 2 and 21 are vague and indefinite because they recite the word "initiator" but it is not clear what is being initiated.

Claims 5-6 are vague and indefinite because they recite the phrase "CBP binding element" and the acronym "CBP" appears to denote multiple proteins in the art, including CREB binding protein, cAMP binding protein and CAT binding protein. It is not clear which protein is meant by "CBP".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6, 15 and 17-20 are rejected under 35 U.S.C. 102(a) as being anticipated by (Flotte et al) U.S. Patent No. 6,461,606, 10/8/2002 as evidenced by Morral et al (1997, Human Gene therapy, Vol. 8. No, 10, pages 1275-1286)

Flotte et al teach adeno-associated virus (AAV) vectors for gene therapy comprising synthetic promoters and synthetic enhancers. Flotte et al teach that enhancer elements can be included in the vector that function to increase transcription levels of human alpha-1-anti-trypsin (hAAT) (see column 5, lines 56-62 and column 6, lines 9-22 and column 81, claim 7, for example) which reads on a nucleic acid segment comprising a synthetic promoter/enhancer wherein the promoter/enhancer is optimized for use in gene therapy. Flotte et al teach that the synthetic enhancer can include SP-1 (see column 6, lines 15-23, for example)

Morral et al teach that vectors comprising human alpha1-antitrypsin as a reporter protein were administered to several mouse strains, and that some mouse strains developed antibodies to hAAT (see page 1277, left column, 4th paragraph and page 1282, left column, 2nd paragraph, in particular). Therefore, the vector taught by Flotte et al inherently potentially encodes an immunogenic polypeptide. Flotte et al teach that the synthetic promoter and enhancer elements for expression of hAAT are in AAV vectors and AAV vector plasmids (see column 7, lines 65-67 bridging to column 8, lines, 1-10 and column 9, lines 34-45), which reads on the claimed nucleic acid segment potentially encoding an immunogenic polypeptide in a circular expression element (plasmid

vector). Flotte et al teach that the vectors comprising hAAT can be prepared in a pharmaceutical formulation and administered to an animal in need of such treatment (see column 8, lines 51-61, for example) which reads on the claimed nucleic acid segment being comprised in a pharmaceutical composition.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Kim (U.S. Patent No 6,525,189, filed 10/16/2000).

Kim teaches an expression construct that comprises a promoter and optimized enhancer domains for driving robust gene expression for gene therapy (see column 6, lines 7-13, and column 15, lines 1-13, in particular). Kim teaches that artificial enhancer domains that include multimerized domain can be synthesized to increase promoter activity (see column 5, lines 63-67 bridging to column 6, lines 1-6 and lines 37-46, and column 8, lines 16-20 for example), which reads on a nucleic acid segment comprising a synthetic promoter/enhancer that is optimized for use in gene therapy.

Claims 1, 15, 17-20 are rejected under 35 U.S.C. 102(a) as being anticipated by (Sykes and Johnston) U.S. Patent Application Publication No. 2002/0146733.

Sykes and Johnston teach linear and circular expression elements for gene expression comprising promoter sequences with enhancer sequences that can be obtained by synthesis and can be optimized for use as genetic vaccines (see paragraphs 0009, 0012, 0019, 0037, 0043-0044), which reads on a nucleic acid

segment comprising a synthetic promoter/enhancer that is optimized for use in genetic immunization. Sykes and Johnston teach that the expression elements can comprise open reading frames encoding antigens for allergenic, parasitic or pathogenic organisms, like HIV (see paragraph 0185, for example), which reads on the claimed linear and circular expression elements further comprise a nucleic acid segment encoding an immunogenic peptide or polypeptide. Sykes and Johnston teach that the claimed nucleic acid can be defined as a vector or a genetic immunization vector (see paragraph 0306). Sykes and Johnston teach that the elements can be combined with an adjuvant and used to vaccinate an organism (see paragraphs 0318-0323), which reads on the claimed nucleic acid segment comprised in a pharmaceutical composition.

Claims 1, 15, 17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,900,018, filed 2/15/2002.

The applied reference has a common inventor (S. A. Johnston) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Patent '018 teaches teach linear and circular expression elements for gene expression comprising promoter sequences with enhancer sequences that can be

obtained by synthesis and can be optimized for use as genetic vaccines (see columns 1, lines 56-65, column 2, lines 25-35, column 4, lines 44-67, column 8, lines 54-67, and column 9, lines 14-20, in particular) which reads on a nucleic acid segment comprising a synthetic promoter/enhancer that is optimized for use in genetic immunization. Patent '018 teach that the expression elements can comprise open reading frames encoding antigens for allergenic, parasitic or pathogenic organisms, like HIV (see column 31, lines 45-65, for example), which reads on the claimed linear and circular expression elements further comprise a nucleic acid segment encoding an immunogenic peptide or polypeptide. Patent '018 teach that the claimed nucleic acid can be defined as a vector or a genetic immunization vector (see column 50, lines 1-15). Patent '018 teach that the elements can be combined with an adjuvant and used to vaccinate an organism (see column 52, lines 29-65), which reads on the claimed nucleic acid segment comprised in a pharmaceutical composition.

Claims 1, 15, 17-20 are also rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent Application Publication No. 2002/0160402, 10/31/2002, now U.S Patent 6,900,018. The teachings of Publication No. 2002/0160402 are as described for the above rejection.

Claims 1, 15, 17-19 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent No. 6,410,241, issued 6/25/2002.

Patent '241 teaches linear and circular expression elements for gene expression comprising promoter sequences with enhancer sequences that can be obtained by synthesis and can be optimized for use as genetic vaccines (see columns 1, lines 56-65, column 2, lines 25-35 and 63-67, column 4, lines 44-67, column 8, lines 54-67, and column 9, lines 15-20, in particular) which reads on a nucleic acid segment comprising a synthetic promoter/enhancer that is optimized for use in genetic immunization. Patent '241 teaches that the expression elements can comprise open reading frames encoding antigens for allergenic, parasitic or pathogenic organisms, like HIV (see column 31, lines 63-67 bridging to column 32, lines 1-4, for example), which reads on the claimed linear and circular expression elements further comprise a nucleic acid segment encoding an immunogenic peptide or polypeptide. Patent '241 teaches that the claimed nucleic acid can be defined as a vector or a genetic immunization vector (see column 50, lines 14-26). Patent '241 teaches that the elements can be combined with an adjuvant and used to vaccinate an organism (see column 52, lines 45-67), which reads on the claimed nucleic acid segment comprised in a pharmaceutical composition.

Claims 1, 15, 17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 7,018,833.

The applied reference has a common inventor (S.A. Johnston) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention

disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Patent '833 teaches linear and circular expression elements for gene expression comprising promoter sequences with enhancer sequences that can be obtained by synthesis and can be optimized for use as genetic vaccines (see column 1, lines 55-65, column 2, lines 25-35 and 63-67, column 4, lines 44-67, column 8, lines 54-67, and column 9, lines 18-25, in particular) which reads on a nucleic acid segment comprising a synthetic promoter/enhancer that is optimized for use in genetic immunization. Patent '833 teaches that the expression elements can comprise open reading frames encoding antigens for allergenic, parasitic or pathogenic organisms, like HIV (see column 31, lines 63-67 bridging to column 32, lines 1-5, for example), which reads on the claimed linear and circular expression elements further comprise a nucleic acid segment encoding an immunogenic peptide or polypeptide. Patent '833 teaches that the claimed nucleic acid can be defined as a vector or a genetic immunization vector (see column 50, lines 20-34). Patent '833 teaches that the elements can be combined with an adjuvant and used to vaccinate an organism (see column 52, lines 55-67 bridging to column 53, lines 1-5), which reads on the claimed nucleic acid segment comprised in a pharmaceutical composition.

Claims 1, 15, 17-19 are also rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent Application Publication No. 2002/0155508, 10/24/2002, now

U.S Patent 7,018,833. The teachings of Publication No. 2002/0155508 are as described for the above rejection.

Claims 1, 15, 17-20 are rejected under 35 U.S.C. 102(a) as being anticipated by (Sykes and Johnston) U.S. Patent Application Publication No. 2002/0150940, 10/17/2002.

Sykes and Johnston (2002) teach linear and circular expression elements for gene expression comprising promoter sequences with enhancer sequences that can be obtained by synthesis and can be optimized for use as genetic vaccines (see paragraphs 0009, 0012, 0019, 0037, 0043-0044) which reads on a nucleic acid segment comprising a synthetic promoter/enhancer that is optimized for use in genetic immunization. Sykes and Johnston teach that the expression elements can comprise open reading frames encoding antigens for allergenic, parasitic or pathogenic organisms, like HIV (see paragraph 0185, for example), which reads on the claimed linear and circular expression elements further comprise a nucleic acid segment encoding an immunogenic peptide or polypeptide. Sykes and Johnston teach that the claimed nucleic acid can be defined as a vector or a genetic immunization vector (see paragraph 0306). Sykes and Johnston teach that the elements can be combined with an adjuvant and used to vaccinate an organism (see paragraphs 0318-0323), which reads on the claimed nucleic acid segment comprised in a pharmaceutical composition.

Claim 1 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoag et al (Gene Therapy 1999, Vol. 6, pp 1584-1589).

Hoag et al teach an optimized expression vector comprising the promoter of the clotting Factor IX gene for use in gene therapy (see page 1584, abstract). Hoag et al teach that upstream C/EBPα and GABPα/β binding elements were cloned upstream of the Factor IX promoter and resulted in optimal transcription of luciferase (see page 1585, right column, 1st paragraph and Figure 1, for example), which reads on a nucleic acid segment comprising a synthetic promoter/enhancer that is optimized for use in gene therapy. Absent evidence to the contrary, the gene for luciferase potentially encodes an immunogenic polypeptide.

Claim 21 is rejected under 35 U.S.C. 102(e) as being anticipated by (Price) U.S. Patent 7,018,836.

It is noted that claim 21 does not recite that the nucleic acid segment comprises a synthetic promoter sequence or an optimized promoter sequence.

Price teaches nucleic acids related to the control of transcription comprising a promoter that directs expression of a transcription elongation factor P-TEFb (see column 13, lines 40-55, column 45, lines 56-67). Price discloses that the promoter functions as a start site for RNA synthesis and includes a TATA box and promoter elements upstream and downstream of the transcription start site (see column 47, lines 30-50, for example). Price also teach an assay that reveals that the presence of at least transcription factor TFIIB was required for transcription elongation (see column 84, lines

1-13, in particular) showing that a TFIIB binding element would be inherent in the promoter sequence requiring the presence of TFIIB for function. The teachings of Price read on a nucleic acid segment comprising a promoter sequence comprising regions encoding promoter elements including a TATA box, a TFIIB binding element, and initiator, a downstream promoter element and an upstream binding element.

Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Struhl (1995, Ann. Rev. of Genetics Vol. 29, pages. 651-674.

Struhl describes yeast transcriptional regulator mechanisms including promoter elements comprised of TATA and initiator elements (se page 652, 1st paragraph). Struhl teaches that a TFIIB site spans the region between the TATA box and the initiation site. Struhl also teaches that yeast promoters contain protein binding negative regulatory elements that are upstream of upstream elements and can also be downstream of the initiation sites (see page 653, 2nd and 3rd paragraphs, in particular).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 16 is rejected under 35 U.S.C. 103(a) as being obvious over (Sykes and Johnston) U.S. Patent Application Publication No. 2002/0146733 in view of Wahren et al (Vaccine, 2002. Vol. 20, No. 15, pages 1988-93)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claim 15 is drawn to a nucleic acid segment comprising a synthetic promoter/enhancer that is optimized for use in genetic immunization and comprising a nucleic acid segment encoding an immunogenic peptide or polypeptide which is HIV gp120.

Sykes and Johnston teach linear and circular expression elements for gene expression comprising promoter sequences with enhancer sequences that can be obtained by synthesis and can be optimized for use as genetic vaccines (see paragraphs 0009, 0012, 0019, 0037, 0043-0044). Sykes and Johnston teach that the expression elements can comprise open reading frames encoding antigens for allergenic, parasitic or pathogenic organisms, like HIV (see paragraph 0185, for example).. Sykes and Johnston teach that the claimed nucleic acid can be defined as a vector or a genetic immunization vector (see paragraph 0306). Sykes and Johnston teach that the elements can be combined with an adjuvant and used to vaccinate an organism (see paragraphs 0318-0323).

Sykes and Johnston do not teach that the HIV antigen is a HIV gp120.

Wahren et al teach HIV subtypes used for induction of immune responses. Wahren et al teach that the first large scale HIV vaccine trials were based on the HIV envelope glycoprotein 160, which includes the variable gp120 region (see page 1988, right column, 1st paragraph). Wahren et al further teach that HIV has multiple subtypes and gp120 has five variable regions which were investigated for potential sites of interest. Wahren et al teach that vaccination with subtype B induces partial protection in half of the animal models. Wahren et al also teach that the HIV envelope protein mediates strong immunogenicity with some clinical effect (see page 1993, left column, 5th and 6th paragraphs)

It would be obvious to one of ordinary skill in the art include a gene segment encoding HIV gp-120 in a genetic vaccine because Sykes and Johnston teach that an

HIV antigen is included in a nucleic acid segment intended for a genetic vaccine and Wahren et al use HIV gp120 in experimental genetic vaccines. The motivation to do so is the expected benefit of being able to induce an immunogenic effect against HIV and potential protection against HIV challenge as exemplified by Wahren et al and suggested by Sykes and Johnston. HIV gp120 is art-recognized as potential target for HIV vaccines. There is reasonable expectation of success in using the HIV gp120 as an immunogenic polypeptide because it has worked previously for Wahren et al. Given the teachings of the prior art and the level of skill of the ordinary skilled artisan at the time the invention was made, it must be considered that said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claim 16 is rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,900,018, filed 2/15/2002 in view of Wahren et al (Vaccine, 2002. Vol. 20, No. 15, pages 1988-93)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed

in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claim 15 is drawn to a nucleic acid segment comprising a synthetic promoter/enhancer that is optimized for use in genetic immunization and comprising a nucleic acid segment encoding an immunogenic peptide or polypeptide which is HIV gp120.

The teachings of Patent '018 are described above. Patent '018 does not teach that the HIV antigen is a HIV gp120.

Wahren et al teach HIV subtypes used for induction of immune responses. Wahren et al teach that the first large scale HIV vaccine trials were based on the HIV envelope glycoprotein 160, which includes the variable gp120 region (see page 1988, right column, 1st paragraph). Wahren et al further teach that HIV has multiple subtypes and gp120 has five variable regions which were investigated for potential sites of interest. Wahren et al teach that vaccination with subtype B induces partial protection in half of the animal models. Wahren et al also teach that the HIV envelope protein mediates strong immunogenicity with some clinical effect (see page 1993, left column, 5th and 6th paragraphs)

It would be obvious to one of ordinary skill in the art include a gene segment encoding HIV gp-120 in a genetic vaccine because Patent '018 teach that an HIV antigen is included in a nucleic acid segment intended for a genetic vaccine and Wahren et al use HIV gp120 in experimental genetic vaccines. The motivation to do so is the expected benefit of being able to induce an immunogenic effect against HIV and potential protection against HIV challenge as exemplified by Wahren et al and suggested by Patent '018. HIV gp120 is art-recognized as potential target for HIV vaccines. There is reasonable expectation of success in using the HIV gp120 as an immunogenic polypeptide because it has worked previously for Wahren et al. Given the teachings of the prior art and the level of skill of the ordinary skilled artisan at the time the invention was made, it must be considered that said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claim 16 is rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,410,241, issued 6/25/2002 in view of Wahren et al (Vaccine, 2002. Vol. 20, No. 15, pages 1988-93)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an

invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claim 15 is drawn to a nucleic acid segment comprising a synthetic promoter/enhancer that is optimized for use in genetic immunization and comprising a nucleic acid segment encoding an immunogenic peptide or polypeptide which is HIV gp120.

The teachings of Patent '241 are described above. Patent '241 does not teach that the HIV antigen is a HIV gp120.

Wahren et al teach HIV subtypes used for induction of immune responses. Wahren et al teach that the first large scale HIV vaccine trials were based on the HIV envelope glycoprotein 160, which includes the variable gp120 region (see page 1988, right column, 1st paragraph). Wahren et al further teach that HIV has multiple subtypes and gp120 has five variable regions which were investigated for potential sites of interest. Wahren et al teach that vaccination with subtype B induces partial protection in half of the animal models. Wahren et al also teach that the HIV envelope protein

mediates strong immunogenicity with some clinical effect (see page 1993, left column, 5th and 6th paragraphs)

It would be obvious to one of ordinary skill in the art include a gene segment encoding HIV gp-120 in a genetic vaccine because Patent '241 teach that an HIV antigen is included in a nucleic acid segment intended for a genetic vaccine and Wahren et al use HIV gp120 in experimental genetic vaccines. The motivation to do so is the expected benefit of being able to induce an immunogenic effect against HIV and potential protection against HIV challenge as exemplified by Wahren et al and suggested by Patent '241. HIV gp120 is art-recognized as potential target for HIV vaccines. There is reasonable expectation of success in using the HIV gp120 as an immunogenic polypeptide because it has worked previously for Wahren et al. Given the teachings of the prior art and the level of skill of the ordinary skilled artisan at the time the invention was made, it must be considered that said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claim 16 is rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 7,018,833 in view of Wahren et al (Vaccine, 2002. Vol. 20, No. 15, pages 1988-93)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claim 15 is drawn to a nucleic acid segment comprising a synthetic promoter/enhancer that is optimized for use in genetic immunization and comprising a nucleic acid segment encoding an immunogenic peptide or polypeptide which is HIV gp120.

The teachings of Patent '833 are described above. Patent '833 does not teach that the HIV antigen is a HIV gp120.

Wahren et al teach HIV subtypes used for induction of immune responses. Wahren et al teach that the first large scale HIV vaccine trials were based on the HIV envelope glycoprotein 160, which includes the variable gp120 region (see page 1988, right column, 1st paragraph). Wahren et al further teach that HIV has multiple subtypes and gp120 has five variable regions which were investigated for potential sites of interest. Wahren et al teach that vaccination with subtype B induces partial protection in

half of the animal models. Wahren et al also teach that the HIV envelope protein mediates strong immunogenicity with some clinical effect (see page 1993, left column, 5th and 6th paragraphs)

It would be obvious to one of ordinary skill in the art include a gene segment encoding HIV gp-120 in a genetic vaccine because Patent '833 teach that an HIV antigen is included in a nucleic acid segment intended for a genetic vaccine and Wahren et al use HIV gp120 in experimental genetic vaccines. The motivation to do so is the expected benefit of being able to induce an immunogenic effect against HIV and potential protection against HIV challenge as exemplified by Wahren et al and suggested by Patent '833. HIV gp120 is art-recognized as potential target for HIV vaccines. There is reasonable expectation of success in using the HIV gp120 as an immunogenic polypeptide because it has worked previously for Wahren et al.

Given the teachings of the prior art and the level of skill of the ordinary skilled artisan at the time the invention was made, it must be considered that said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claim 16 is rejected under 35 U.S.C. 103(a) as being obvious over (Sykes and Johnston) U.S. Patent Application Publication No. 2002/0150940, 10/17/2002 in view of Wahren et al (Vaccine, 2002. Vol. 20, No. 15, pages 1988-93)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art

only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The teachings of Sykes and Johnston (2002) are described above. Sykes and Johnston (2002) do not teach that the HIV antigen is a HIV gp120.

Wahren et al teach HIV subtypes used for induction of immune responses. Wahren et al teach that the first large scale HIV vaccine trials were based on the HIV envelope glycoprotein 160, which includes the variable gp120 region (see page 1988, right column, 1st paragraph). Wahren et al further teach that HIV has multiple subtypes and gp120 has five variable regions which were investigated for potential sites of interest. Wahren et al teach that vaccination with subtype B induces partial protection in half of the animal models. Wahren et al also teach that the HIV envelope protein

mediates strong immunogenicity with some clinical effect (see page 1993, left column, 5th and 6th paragraphs)

It would be obvious to one of ordinary skill in the art include a gene segment encoding HIV gp-120 in a genetic vaccine because Sykes and Johnston (2002) teach that an HIV antigen is included in a nucleic acid segment intended for a genetic vaccine and Wahren et al use HIV gp120 in experimental genetic vaccines. The motivation to do so is the expected benefit of being able to induce an immunogenic effect against HIV and potential protection against HIV challenge as exemplified by Wahren et al and suggested by Sykes and Johnston (2002). HIV gp120 is art-recognized as potential target for HIV vaccines. There is reasonable expectation of success in using the HIV gp120 as an immunogenic polypeptide because it has worked previously for Wahren et al.

Given the teachings of the prior art and the level of skill of the ordinary skilled artisan at the time the invention was made, it must be considered that said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura McGillem, PhD
4/6/2006

DAVID GUZO
PRIMARY EXAMINER

Notice to Comply	Application No.	Applicant(s)	
	10/781,055	JOHNSTON ET AL.	
	Examiner	Art Unit	
	Laura McGillem	1636	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: The specification (Examples 1-3) contains multiple nucleic acid sequences that have not been identified by SEQ ID NO.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

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